UNITED STATES DEPARTMENT OF AGRICULTURE FOOD SAFETY AND INSPECTION SERVICE WASHINGTON, DC

FSIS DIRECTIVE

5420.1, Revision 2

7/20/05

HOMELAND SECURITY THREAT CONDITION RESPONSE - FOOD DEFENSE VERIFICATION PROCEDURES

I. PURPOSE

A. This directive details the emergency Food Defense Verification Procedures that inspection program personnel will follow when a threat condition Yellow, Orange, or Red is declared by the Department of Homeland Security. Inspection program personnel should begin implementing these procedures only when instructed to do so by the District Manager (DM) or designee. In that event, inspection program personnel are to follow the instructions in this directive for the duration of the declared heightened threat condition. Because inspection program personnel are the first line of defense in food safety, they are in a unique position to witness and identify unusual situations such as food security issues.

B. This directive also:

- establishes how threat condition declarations will be communicated to field personnel,
- provides specific instructions to field personnel on how to respond to threat condition declarations,
- identifies procedures to effectively address and resolve noted security concerns in order to ensure food security and protect public health, and
- provides instructions for the Inspector-in-Charge (IIC) to inquire as to whether an establishment has developed, implemented, tested, assessed and maintained a food defense plan.
- C. This directive does not address procedures to be followed in the event of an actual terrorist attack on an establishment. Should such an attack occur, measures should be taken immediately by IIC to ensure the safety of inspection program personnel and to notify the District Office (DO). Subsequently, the DO will notify the appropriate local authorities. Also, the DO may request the activation of the FSIS Emergency Management Committee (EMC) if necessary through the senior executive leadership in Office of Field Operations (OFO) (See FSIS Directive 6500.1 Emergency Incidence Response).

DISTRIBUTION: Inspection Offices: T/A Inspectors:

Plant Mgt.; T/A Plant Mgt.; TRA; ABB;

TSC; Import Offices

OPI: OPPED

II. CANCELLATION

FSIS Directive 5420.1, Revision 1 dated 1/26/05 FSIS Notice 19-05, dated 3/23/05

III. REASON FOR REISSUANCE

This directive is reissued in its entirety to clarify how inspection program personnel are to document findings when they find a food defense breach or concern and there is evidence of product adulteration (i.e., documenting under the "T" trend indicator). This reissuance also incorporates the instructions from FSIS Notice 19-05, Clarification for FSIS Directive 5420.1, Revision 1 – Homeland Security Threat Condition Repsonse – Food Defense Verification Procedures, and to provide verification procedures related to a voluntary Food Defense Plan.

IV. REFERENCES

9 CFR part 300 to end Directive 6500.1, Emergency Incidence Response FSIS Directive 6000.1, Responsibilities Related to Foreign Animal Diseases (FADs) and Reportable Conditions. FSIS Directive 5000.1, Revision 1

V. BACKGROUND

In 2002, the White House Office of Homeland Security established a Homeland Security Advisory System based on color to provide a comprehensive and effective means to disseminate information regarding the risk of terrorist acts to Federal, State, and local authorities and to the American people. A declaration of a Threat Condition Elevated (Yellow) by the Department of Homeland Security indicates that there is an elevated risk of terrorist attacks. A declaration of a Threat Condition High (Orange) indicates that there is a high risk of terrorist attacks. A declaration of a Threat Condition Severe (Red) reflects a severe risk of terrorist attacks. While the threat may or may not involve the nation's food supply, it is imperative that certain actions be immediately undertaken by inspection program personnel during such threat conditions to ensure the safety of meat, poultry and egg products. Given what is required in responding to a credible threat of a terrorist attack, inspection program personnel must clearly understand their roles and what will be required of them in order to properly respond to that threat.

VI. NOTIFICATION

A. In the event of a declaration of any threat condition:

- Elevated (Yellow), when there is a significant risk of terrorist attacks
- High (Orange), when there is a high risk of terrorist attacks, or
- Severe (Red) when there is a severe risk of terrorist attacks,

by the Department of Homeland Security, Office of Food Defense and Emergency Response (OFDER) will inform the FSIS Administrator and senior executive leadership of all FSIS program areas. The Office of the Administrator will issue an e-mail letter to all employees notifying them of the heightened threat condition.

- B. The DO will notify the IIC at all establishments, or at specific high risk establishments when a specific threat has been identified by the Agency at the time of the declaration, to conduct Food Defense Verification Procedures and to modify his or her Performance Based Inspection System (PBIS) scheduled activities or egg verification methodology as set forth in Paragraph VII of this directive for the specified threat condition. The IIC will notify the establishment management of the threat condition and the implementation of the Food Defense Verification Procedures.
- C. The downgrading of a threat condition will be communicated by OFDER to the DO through the senior executive leadership in OFO. Upon receiving such notification from the DO, the IIC will return to the PBIS scheduled activities or egg verification methodology unless otherwise indicated by the DO and advise the establishment management that procedures at the lower threat condition have resumed.

VII. SPECIFIC THREAT CONDITION ACTIVITIES

When instructed by the IIC, inspection program personnel in meat, poultry, and egg establishments will perform the Food Defense Verification Procedures, instead of certain scheduled other consumer protection (OCP) procedures, as follows:

NOTE: Inspection program personnel assigned to meat and poultry establishments will continue to perform all food safety activities assigned by PBIS and inspection program personnel assigned to egg products establishments will continue to perform all food safety activities as required by current regulatory and policy requirements.

A. Threat Condition Elevated (Yellow), High (Orange) or Severe (Red) with no specific threat to the food and agricultural sector.

1. Inspection program personnel in meat and poultry establishments are to randomly perform one of the Food Defense Verification Procedures listed in Section IX. C., Inspection System Procedure (ISP) code 08S03-08S13, daily for the duration of the threat condition. They are to perform this procedure instead of one of the following scheduled 04 procedures: ISP code 04A01, 04A02, 04A03, 04A04, 04B01, 04B02, 04B03, 04B04, or 04C01. For example, during a threat condition Orange with no specific threat to the food and agricultural sector, if ISP codes 04A01 and 04B04 are scheduled for Tuesday, then inspection program personnel may perform 08S05 in place of 04A01 on Tuesday. If there are no scheduled 04 procedures on a given day, inspection program personnel are to randomly perform one of the ISP codes 08S03-08S13.

- 2. Inspection program personnel in egg products processing establishments are to randomly perform one of the Food Defense Verification Procedures listed in Section IX. C., daily for the duration of the threat condition within the established tour of duty after all food safety procedures are performed.
- 3. Inspection program personnel are to perform the Food Defense Verification Procedures as UNSCHEDULED procedures within the established tour of duty and after all food safety procedures are performed.

B. Threat Condition High (Orange) with a specific threat to the food and agriculture sector.

- 1. Inspection program personnel in meat and poultry establishments are to randomly perform three of the procedures from the Food Defense Verification Procedures (ISP codes 08S08-08S13 identified in Section IX. C.) daily for the duration of the threat condition. They are to perform these procedures instead of the scheduled 04 procedures (see list in Section VII. A. 1.). If there are no scheduled 04 procedures on a given day, inspection program personnel are to randomly perform three of the ISP codes 08S08-08S13.
- 2. Inspection program personnel in egg products processing establishments are to randomly perform three of the procedures from the Food Defense Verification Procedures daily for the duration of the threat condition within the established tour of duty after all food safety procedures are performed. Inspection program personnel are to select any three from the list of procedures from number 6 (ISP 08S08) Incoming Raw Materials to number 11 Employee Behavior (ISP 08S13).
- 3. Inspection program personnel in meat and poultry establishments and in egg products processing establishments are also to perform any additional measures prescribed by the DO based on the information received about a particular threat to a product or process.
- 4. The three Food Defense Verification Procedures should be performed as UNSCHEDULED procedures within the established tour of duty and after all food safety procedures are performed.

C. Threat Condition Severe (Red) with a specific threat to the food and agriculture sector.

1. Inspection program personnel in meat and poultry establishments are to perform ALL of the procedures from the Food Defense Verification Procedures (ISP codes 08S03-08S13 identified in Section IX. C.) daily for the duration of the threat condition. They are to perform these procedures instead of the scheduled 04 procedures (see list in Section VII. A. 1.). If there are no scheduled 04 procedures on a given day, inspection program personnel are to perform all of the ISP codes 08S03-08S13.

- 2. Inspection program personnel in egg products processing establishments are to perform ALL of the Food Defense Verification Procedures listed in Section IX. C. daily for the duration of the threat condition within the established tour of duty after all food safety procedures are performed.
- 3. The IIC will receive specific instructions from the DO on other measures that must be taken based on information received about the specific threat to a product or process. Such measures may include sampling of specific products, if warranted, to ensure public health is protected, and the taking of regulatory actions.
- 4. The DO will deploy inspection program personnel to establishments where the products named in the threat condition are being produced to ensure that FSIS has an on-site presence during any type of operational activity.
- 5. If inspection program personnel are unable to complete ALL Food Defense Verification Procedures along with the food safety procedures within their normal tour of duty, they are to contact the Frontline Supervisor for guidance regarding which food safety procedures are to be performed or if overtime will be approved.

VIII. FOOD DEFENSE PLAN

- A. At the first weekly PBIS meeting after receipt of this revised directive, IICs are to discuss whether the establishment has a food defense plan. Establishments are under no obligation to show the plan because of sensitive security information. The IIC should at least:
- 1. discuss whether the establishment has a food defense plan that is written, implemented, tested, assessed and maintained to address the means by which intentional product contamination will be prevented, and that such plan addresses the following food defense concerns:
 - a. general security,

(The related ISP codes are found in Section XI: 08S03, 08S09, 08S11, and 08S13)

b. slaughter and processing security, and

(The related ISP codes are found in Section XI: 08S05, 08S06, 08S08, and 08S12)

c. storage security

(The related ISP codes are found in Section XI: 08S04, 08S07, and 08S10)

2. refer establishment management to the FSIS Food Defense and Emergency Response web site. The web site is located at:

http://www.fsis.usda.gov/Food Security & Emergency Preparedness/index.asp

This web site contains the FSIS Food Security Guidelines for Food Processors, among other food defense information. These guidelines provide security measures that establishments may want to incorporate in a food defense plan.

- 3. inform the establishment that FSIS strongly encourages the establishment to have a written food defense plan that is implemented, tested, assessed and maintained, although the establishment is under no obligation to have such a plan, and there are no specific criteria that the plan must meet.
- B. IICs are to document what was discussed at the meeting in a memorandum of interview, including whether the establishment has a written food defense plan that is implemented, periodically tested, assessed and maintained; maintain the memorandum in the file; and forward copies through supervisory channels.

NOTE: Via FAIM alerts, IICs will be requested to inquire about the establishment's development and implementation of its food defense plan at subsequent weekly meetings. FSIS will provide further information about this process in a FSIS Notice.

IX. FOOD DEFENSE VERIFICATION PROCEDURES

- A. The purpose of the following emergency Food Defense Verification Procedures is to ensure that potential breaches in the security of an establishment that could lead to deliberate contamination are identified and are mitigated, to the maximum extent possible. A potential breach can be any measure that should be implemented to protect plant operations but is found or observed to be missing or not in place. Examples of security breaches include uncontrolled access to a restricted ingredient area; unrestricted access to a gate at a plant; well water is unprotected; or evidence of tampering (holes or cuts) in the packaging of dry ingredients used for mixing.
- B. IICs are to immediately notify the establishment management of any concern. Program personnel are to take immediate action any time product adulteration is observed. In the event product is adulterated, inspection program personnel are to take immediate action as per established policy for adulterated product.
 - C. At a minimum, the IICs will:

1. 08S03 - Outside Premises

Observe the outer perimeter of the establishment to verify that fences and gates (if any) are intact. Verify that entrances to the establishment are secured against unauthorized entry. Special attention should be paid to truck entrance and parking areas, any trucks used to provide on-site dry and cold storage of processing ingredients, and the external portion of silo tanks used to store liquid egg products.

SUGGESTED ACTIVITIES:

 Select one or more areas or departments and observe windows, roof openings and hatches, vent openings, bulk storage tanks to see if they are properly secured, to the extent possible.

- Examples of "properly secured, to the extent possible" include the use of: locks, jimmy plates, seals, alarms, intruder detection sensors, guards, monitored video surveillance, police patrols, adequate interior and exterior lighting, authorized parking systems, identification badge systems, metal doors on the plant exterior, and a system for keeping track of door keys.
 - Safety note: Fire exits must not be locked on the inside.

2. 08S04 - Control/Use of Hazardous Chemicals

Observe the use and storage of any hazardous materials in the establishment, and verify that entry into such storage areas is controlled and that usage logs are maintained and current. Special attention should be paid to cleaning materials, particularly those used in clean-in-place systems, or where there is mixing of bulk products (e.g., storage silos). In addition, the control of laboratory reagents and cultures should be verified.

SUGGESTED ACTIVITIES:

- Observe the handling or storage of one or more hazardous materials (non-food chemicals) to determine whether they are handled and stored in a manner that demonstrates control and appropriately limited access to those hazardous materials.
- Check that materials are properly identified and stored away from edible product, and that entry logs are on file, accurate, and complete. Some examples of measures to reasonably control access to these materials are the use of locks for which only designated employees have a key, or electronic access.
- If the plant maintains inventory records of hazardous materials, compare those records to hazardous materials on hand for accuracy.

3. 08S05 - Live Animals (From Slaughter plants only)

Observe live animals arriving at the establishment for symptoms of diseases that may indicate the introduction of a biological agent (e.g., foot and mouth disease) into the livestock population. Also, promptly notify the Animal and Plant Health Inspection Service (APHIS) when signs of Foreign Animal Diseases (FAD) are noted on livestock or poultry during antemortem and postmortem inspection (See FSIS Directive 6000.1).

SUGGESTED ACTIVITIES:

 Use normal notification procedures for FAD - contact DO and State Health Official or Area Veterinarian-in-Charge. (See FSIS Directive 6000.1) • Public Health Veterinarians (PHVs) should perform antemortem inspection in both meat and poultry slaughter plants, to the extent possible, during threat condition Orange or Red with a specific threat to the food and agriculture sector.

4. 08S06 – Equipment Calibration

Verify the proper calibration of equipment.

SUGGESTED ACTIVITIES:

- Review equipment guidance material and calibration logs to determine whether items are operating as determined by the manufacturer.
 - Verify the calibration of equipment.
- Verify security, procedures, and location surrounding alternative equipment sources (e.g., X-ray equipment, radiation equipment).

5. 08S07 – Loading Docks/Shipping

Observe loading dock areas and vehicular traffic in and out of the establishment. Report all unattended deliveries on loading docks and unmarked vehicles parked on the premises to establishment management immediately. Make facility management aware of the importance of ensuring that truck drivers do not have unsupervised access to product receiving and storage areas. Suggest that facility management ensure that dry and cold products stored in on-site trailers are secured; that trailers are parked in a restricted access area of the facility; and that facility security staff routinely check the trailers. Special attention should be paid to deliveries of liquid egg products to storage silos, of combo bins of meat trim, and of dry ingredients.

SUGGESTED ACTIVITIES:

- Check to determine whether the plant has a system to report unattended deliveries on loading docks (e.g. plant has a roster of scheduled deliveries and personnel to verify that each delivery was scheduled and to ensure that unscheduled deliveries are held outside the premise until the shipper is verified).
- Check to determine whether the plant has controlled parking areas to keep the vehicles of visitors and guests at a safe distance from main facility and follows procedures to maintain that control.

6. 08S08 – Incoming Raw Materials

Observe incoming raw materials to verify that deliveries are checked against shipping documents. Special attention should be paid to tanker trucks and totes of liquid egg products; dry ingredients; combo bins of fresh meat trim, or poultry parts; and boxes of frozen trim that will be further processed.

SUGGESTED ACTIVITIES:

- Observe one or more different ingredients or incoming loads of raw materials to determine whether shipping documents/bills of lading are accurate, timely, on file (if documents arrived prior to shipment), and match the incoming materials.
- If an establishment has a tracking/logging system for verifying incoming deliveries against shipping documents/bills of lading, review a random sample of records.

7. 08S09 - Maintenance

Observe maintenance, construction, and repair activity at the establishment to ensure personnel performing such activities are properly identified and authorized to perform such activities. Special attention should be paid to determining whether construction personnel (or any other unauthorized personnel) are denied access to sensitive processing operations where bulk products will be mixed (e.g., grinding, emulsification, dry and cold storage areas, silo tanks, solution preparation areas). In addition, determine whether contract maintenance, third shift personnel, and other similar types of individuals should undergo background screening or are checked by facility security staff, and if not, what impact this has on plant security.

SUGGESTED ACTIVITIES:

- Verify that the establishment has procedures to control the entry of all persons (employees, construction workers, outside contractors, visitors, guests, sales people, truck drivers), such as an identification system, restriction of people movement.
- Evaluate records such as rosters for shifts, if available, to determine whether they are accurate, complete, and indicative of the plant meeting its procedures for identifying personnel and controlling their access to areas within the establishment).

8. 08S10 - Storage Areas

Observe products in cold and dry storage areas for evidence of tampering. Special attention should be paid to bulk product ingredients that will undergo mixing, such as combo bins of meat trim and poultry parts used for grinding or emulsification. Dry ingredients, including spices, breading materials, and those used in injection solution preparations, also should be checked for indication of tampering.

SUGGESTED ACTIVITIES:

- Randomly select a product in a storage area and observe whether the package integrity has been compromised, e.g. look for holes, cuts or any other evidence that may indicate product tampering.
- Evaluate any records that the establishment may maintain on the monitoring of product packaging integrity.

9. 08S11 - Water Systems

Observe the security of the plant's water systems, especially water storage facilities and reuse systems. Check the plant's potable water supply and report any change in the appearance, taste, or odor to the establishment. Special attention should be paid to water used to prepare injection solutions and to water and ice used in emulsification (for the production of deli meats and hot dogs). To a lesser extent, water used to prepare surfactant and antimicrobial agent sprays and as chill tank recharge should also be checked.

SUGGESTED ACTIVITIES:

- Determine whether access to private wells is controlled.
- Determine whether potable water tanks and ice are appropriately secured.
- Determine whether potable water lines in processing areas are inspected for tampering.
- Ask establishment management whether the plant has a plan to notify local health officials if a possible tampering or compromised water supply situation occurs.
- Determine whether water or ice is clear, odorless, and free of visible contamination.

10. 08S12 - Production/Processing

Observe production processes (slaughter, processing, fabrication, packaging) where exposed products are being handled for indications of any possible attempts to introduce contaminants into the product. In particular, observe operations where bulk products are being mixed or stored, such as process monitoring at balance tanks, storage of liquid egg products in silos, grinding/emulsification of meat and poultry products, solution injection in preparation areas, and liquid egg product tanker loading areas. Storage areas for cold and dry ingredients (e.g., combo bins of meat trim and spices, respectively) used in these operations also should be checked.

SUGGESTED ACTIVITIES:

 Check a random sample of equipment to see whether the plant has procedures in place to monitor the operation of the equipment to prevent product tampering. • Check a random process (e.g. slaughter floor, ground beef production area, egg products breaking room) to see whether the plant has procedures in place to monitor the operation of the production process to prevent product contamination.

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- Observe the formulation of one or more batches of product to determine whether plant procedures meet security guidance guidelines.
- Observe whether the plant has a system to evaluate/examine returned goods for evidence of possible tampering before use in salvage or rework.

11. 08S13 - Employee Behavior

Observe the behavior and in-plant movement of establishment employees, especially those who suddenly appear in areas where they are not assigned to work. Encourage establishment management to control employee access to sensitive processing operations (e.g., where bulk products are being mixed). Further, discuss with facility management the importance of raising food security awareness through employee training programs.

SUGGESTED ACTIVITIES:

- Check to determine whether the plant has implemented a system to restrict employee access to appropriate areas (e.g., color-coded uniforms, identification badges, sign out sheets).
- Observe employees who do not have appropriate identification, do not seem like they belong in a given area, or in some other way seem to be out of place or performing inappropriate activities.

X. DOCUMENTATION

Inspection program personnel are to record the performance of the ISP procedures listed in paragraph IX and document findings, in the following manner.

A. Meat and Poultry

- 1. When inspection program personnel perform an 08S procedure and do not find a food security breach or concern, they are to record the procedure as performed by recording trend indicator "A."
- 2. When inspection program personnel perform an 08S procedure and do find a food security breach or food security concern they are to:
 - a. record the procedure as performed by recording:
 - i. trend indicator "S" when there is no evidence of product adulteration,

or

- ii. trend indicator "T" when there is product adulteration,
- b. immediately notify the establishment management and discuss the findings,
- c. prepare a memorandum of interview that describes all potential breaches in security and, if applicable, the product adulteration (including verification of control and disposition of product); provide an explanation of the discussions with establishment management; and refers establishment management to the web site listed in Section VIII. D. above. Write or Type "Sensitive Security Information" at the top of this memo (See Example, Attachment 1), and
- d. provide a copy of the memorandum to the District Analyst and to plant management, and maintain a copy in the file.

B. Egg Products

Inspection program personnel assigned to egg products establishments are to:

- 1. record the performance of these activities in the Remarks section of the "Daily Report of Plant Operations" (PY-203 for liquid egg products and PY-159 for dried egg products);
- 2. prepare a memorandum of interview that describes all potential breaches in security, provides an explanation of the discussions with establishment management, and refers establishment management to the website listed in Section VIII. D. above. Write or Type "Sensitive Security Information" at the top of this memo (See Example, Attachment 1);
- 3. in the event that a food security breach has resulted in adulteration of product, include this fact (including verification of control and disposition of product) and the significance of the breach in the memorandum of interview;
- 4. provide a copy of the memorandum to the District Analyst and to plant management; and
- 5. attach a copy of the memorandum to the "Daily Report of Plant Operations" and maintain it in the file.
- C. The establishment is not under any regulatory obligation to respond. After meeting with plant management and preparing the memorandum of interview, inspection program personnel are to continue the random selection of food security procedures as instructed in paragraph IX. Inspection program personnel are not to perform the same food defense ISP procedure again as a means to determine how the establishment addressed the situation. Only while conducting random food defense procedures should inspection program personnel conduct the same food defense ISP procedure.

D. If inspection program personnel encounter the same potential food security breach or concern while randomly conducting food defense procedures, they are to meet with the establishment management and prepare a second memorandum of interview on this breach. If inspection program personnel, through the random FSIS Directive 5420.1, Revision 2

performance of food defense procedures, encounter the same potential food security breach or concern a third time, they are to meet once again with the establishment management and prepare a third memorandum of interview. If the establishment expresses no intention to address the breach or concern, inspection personnel should notify the District Office of this situation through the Frontline Supervisor.

E. The District Office will investigate the breach or concern to determine whether other procedures or surveillance activities are necessary and will instruct the appropriate inspection program personnel accordingly.

Direct all questions related to this directive through supervisory channels.

Assistant Administrator

May Salafle-

Office of Policy, Program, and Employee Development

Attachment

FSIS Directive 5420.1, Revision 2 Attachment 1

Memorandum of Interview

Sensitive Security Information

Date Address

On (date) at (time) I conducted a Food Defense Awareness Meeting with (name(s) and title(s) of establishment personnel present) at (establishment name and address).

During the meeting I presented establishment management with the following potential breeches of security:

• (List breaches here)

The following is a description of the discussion held with the establishment management:

• (describe discussion here)

I referred the establishment management to the FSIS Food Security Guidelines for Food Processors for information about additional security measures.

A copy of this Memorandum of Interview will be provided to establishment management and a copy placed in the official USDA file.

(Signature) (Typed name) (Badge Number)